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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,452	05/05/2006	Hengyuan Lang	34056-US-PCT	9887

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EXAMINER	
WILLIS, DOUGLAS M	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,452	LANG ET AL.	
	Examiner	Art Unit	
	DOUGLAS M. WILLIS	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims / Priority

Claims 1-61 are pending in the current application. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/US2004/23726, filed July 23, 2004, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/490,096, filed July 25, 2003.

Restrictions

Restriction is required under 35 U.S.C. § 121 and § 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-37 and 54-57, is drawn to compounds and pharmaceutical compositions of formula (I), possessing a benzenecarboxamide core where Y = -L-R^3 and L = -C(=O)NH or -NH(C=O), and X = -dihydroquinazolinyl or -quinazolinyl and an article of manufacture, comprising packaging material, a compound of claim 1... and a label.

Group II, claims 1-37 and 54-57, is drawn to compounds and pharmaceutical compositions of formula (I), possessing a benzenecarboxamide core where Y = -L-R^3 and L = -C(=O)NH or -NH(C=O), and X = -phenyl, -pyridinyl, or -pyrimidinyl and an article of manufacture, comprising packaging material, a compound of claim 1... and a label.

Group III, claims 1-37 and 54-57, is drawn to compounds and pharmaceutical compositions of formula (I), possessing a benzenecarboxamide core where Y and X are recited moieties not encompassed or previously mentioned and an article of manufacture, comprising packaging material, a compound of claim 1... and a label. **NOTE:** *If group III is elected, further restriction may be required.*

Group IV, claims 38-40, 45, 46, 49, 50 and 58, is drawn to methods of treating,

preventing… symptoms of p38 kinase-mediated diseases or disorders and inhibiting p38 kinases, comprising administering or contacting p38 kinase with… a compound of claim 1. **NOTE:** *If group IV is elected, further restriction will limit scope to one of the compound groups I-III.*

Group V, claims 41, 42 and 59, is drawn to a method of inhibiting the expression of inducible proinflammatory proteins, comprising administering… a compound of claim 1. **NOTE:** *If group V is elected, further restriction will limit scope to one of the compound groups I-III.*

Group VI, claims 43, 44 and 60, is drawn to a method of treating, preventing… symptoms of diseases or disorders associated with inducible proinflammatory proteins, comprising administering… a compound of claim 1. **NOTE:** *If group VI is elected, further restriction will limit scope to one of the compound groups I-III.*

Group VII, claims 47, 48, 51, 52 and 61, is drawn to methods of treating, preventing… symptoms of a cytokine mediated disease or disorder and of mediating cytokine response, comprising administering… a compound of claim 1. **NOTE:** *If group VII is elected, further restriction will limit scope to one of the compound groups I-III.*

Group VIII, claim 53, is drawn to a method of inhibiting inflammatory response, comprising administering… a compound of claim 1. **NOTE:** *If group VIII is elected, further restriction will limit scope to one of the compound groups I-III.*

NOTE: *Applicant is required to elect a provisional species,* ***for searching purposes and prosecution on the merits only,*** *for any of the groups selected from above.*

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in PCT Rule 13.2, the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled "where a group of inventions is claimed in one and the same international application only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art, so linked, as to form a single general inventive concept.

The 'special technical feature' among all groups is a compound of formula (I), particularly possessing a benzenecarboxamide core. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding 'special technical feature' for the following reasons: a) a search of the benzenecarboxamide core gave numerous iterations in STN, indicating that benzenecarboxamides are known and b) WO 03/033482 [pp. 1-4], cited in the international search report, teaches the use of the compounds of formula (I) as p38 kinase inhibitors [p. 1, lines 6-7]. Consequently, the compounds of formula (I) do not share a 'special technical feature' with neither the various processes for their use, as recited in claims 38-53 and 58-60, nor the article of manufacture comprising them, as recited in claim 57, and do not relate to a single general inventive concept under PCT Rule 13.1.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102,

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. A compound having formula (I), wherein… [claims 1-37 and 54-56]

If applicant elects Group I, Group II or Group III, the examiner requires applicant to elect a single species clearly identifying: a) a compound of formula (I), including a

detailed explanation of how all variables of formula I are read upon and b) an additive selected from those listed in claim 56.

B. A method of..., comprising administering... a compound of claim 1. [claims 38-53 and 58-60]

If applicant elects any one of the groups listed as Groups IV-X, the examiner requires applicant to elect a single species clearly identifying: a) a compound of formula (I), including a detailed explanation of how all variables of formula I are read upon and b) a disease, disorder, compound or enzyme selected from those listed in claims 40, 44, 46, or 48, where applicable.

The claims are deemed to correspond to the species listed above in the following manner: Groups I-III - claims 2-37, 55 and 56; Group IV - claims 39, 40, 45, 46 and 50; Group V - claim 42; Group VI - claim 44; Group VII - claims 48 and 52; and Group VIII - claim 53. The following claim(s) are generic: Groups I-III - claims 1, 54 and 57; Group IV - claims 1, 38, 49 and 58; Group V - claims 1, 41 and 59; Group VI - claims 1, 43 and 60; Group VII - claims 1, 47, 51 and 61; and Group VIII - claim 53.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding 'special technical features' for the following reasons: a) a search of the benzamide core gave numerous iterations indicating that benzamides are known and b) WO 03/033482 [pp. 1-4], cited in the international search report, teaches the use of the compounds of formula (I) as p38 kinase inhibitors [p. 1, lines 6-7].

There is an examination and search burden for these patentably distinct species due to

their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or 35 U.S.C. § 112, first paragraph.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Applicant is required, in reply to this action, to elect a single species, ***for searching purposes and prosecution on the merits only***, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include: **(i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143)** and **(ii) identification of the claims encompassing the elected invention.**

A telephone call was made to Mr. Peter Waibel on May 9, 2008 to request an oral election to the above species requirement, but resulted in a voice mail message. On May 12, 2008, restriction requirement was made via mail correspondence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Friday from 8:00-5:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan, can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. M. W./
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161